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SUPPL

Phase III MabThera maintenance trial in lymphoma shows positive results earlier than expected

RECEIVE

Roche has been informed by the European Organisation for Research and Treatment of Cancer (EORTC) that a phase III study in relapsed indolent non-Hodgkin's lymphoma (NHL) evaluating the use of MabThera (rituximab) as maintenance treatment has shown positive results earlier than expected. MabThera maintenance therapy is administered over two years and aims to prevent disease recurrence.

"Our study confirms that MabThera maintenance therapy is beneficial for patients that have already received MabThera as part of their initial therapy" said lead investigator, Professor Marinus van Oers M.D., from the Academic Medical Center of the University of Amsterdam, "The full results of the trial will be presented as an oral presentation at this year's annual conference of the American Society of Hematology (ASH) in Atlanta."

Non-Hodgkin's lymphoma affects 1.5 million people worldwide. Indolent NHL, representing about 45% of NHL patients, is a slow developing but serious cancer of the lymphatic system.

"We look forward to the presentation of the full trial results in December", said Eduard Holdener, Head of Pharma Development at Roche. "Based on this new information MabThera maintenance therapy could well become the new standard treatment in this disease."

Roche is currently preparing an application to the European Authorities to request a label extension for maintenance therapy, expected to be submitted in the fourth quarter 2005, making this treatment option available to all patients.

<sup>&</sup>lt;sup>1</sup> European Organization for Research and Treatment of Cancer (EORTC) Study 20981

#### About the study

The international cooperative group phase III trial was conducted in 18 countries and recruited 465 patients with relapsed indolent NHL. Patients were randomized to receive either six cycles of MabThera in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) chemotherapy, or CHOP chemotherapy alone. Patients who responded to initial treatment were then randomised to MabThera maintenance therapy (one infusion every three months for two years) or no further treatment.

A pre-planned analysis in early 2004 showed that induction treatment with MabThera plus CHOP was significantly superior to CHOP alone and that two years of MabThera maintenance therapy substantially improved progression-free survival compared to observation. Therefore, the trial was suspended as it had reached both primary endpoints. At that time the results were not mature enough to determine if MabThera maintenance therapy also prolongs progression-free survival for the subgroup of patients who already had received MabThera plus CHOP as initial treatment. The EORTC therefore originally decided to amend the study to evaluate this outstanding question.

An updated analysis of the study data with additional follow-up of approximately 18 months has now demonstrated a significant benefit of MabThera maintenance therapy for patients who initially received MabThera plus CHOP. Consequently, the EORTC, following the recommendation by the Independent Data Monitoring Committee, has stopped the study and decided to report the results at ASH meeting in December.

### About MabThera

MabThera is a therapeutic antibody that binds to a particular protein - the CD20 antigen - on the surface of normal and malignant B-cells. It then recruits the body's natural defences to attack and kill the marked B-cells. Stem cells (B-cell progenitors) in bone marrow lack the CD20 antigen, allowing healthy B-cells to regenerate after treatment and return to normal levels within several months.

MabThera was initially indicated as a single-agent treatment for relapsed or refractory indolent NHL, and received European approval in March 2002 for the treatment of aggressive NHL in combination with CHOP chemotherapy. In August of 2004 MabThera received European approval for first line treatment of Indolent NHL in combination with CVP chemotherapy. MabThera is known as Rituxan in the United States, Japan and Canada, More than 700,000 patients have been treated with MabThera worldwide to date.

Genentech and Biogen Idec co-market MabThera in the United States, and Roche markets

MabThera in the rest of the world, except Japan, where MabThera is co-marketed by Chugai and

## Zenyaku Kogyo Co. Ltd.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-focused healthcare groups in the fields of pharmaceuticals and diagnostics. As a supplier of innovative products and services for the early detection, prevention, diagnosis and treatment of disease, the Group contributes on a broad range of fronts to improving people's health and quality of life. Roche is a world leader in diagnostics, the leading supplier of medicines for cancer and transplantation and a market leader in virology. In 2004 sales by the Pharmaceuticals Division totalled 21.7 billion Swiss francs, while the Diagnostics Division posted sales of 7.8 billion Swiss francs. Roche employs roughly 65,000 people in 150 countries and has R&D agreements and strategic alliances with numerous partners, including majority ownership interests in Genentech and Chugai. Additional information about the Roche Group is available on the Internet (www.roche.com).

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